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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,042	03/18/2002	Joseph Schlessinger	038602-1224	8380
22428	7590	06/21/2005	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			YAO, LEI	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,042

Applicant(s)

SCHLESSINGER ET AL.

Examiner

Lei Yao, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/28/2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: <u>exhibit A</u> . |

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12, drawn to an isolated nucleic acid molecule comprising a nucleic acid sequence encode a polypeptide sequence set forth in SEQ NO: 1 or SEQ ID NO: 2, which encode Pyk2 binding protein.

Group II, claim(s) 13-18, drawn to isolated Pyk2 binding protein wherein said protein is fragment of the protein encoded by sequence set forth in SEQ ID NO: 1 or SEQ ID NO: 2.

Group III, claim(s) 19-22, drawn to an antibody having specific binding affinity to a Pyk2 binding protein and a hybridoma to produce the antibody.

Group IV, claim(s) 23-27, drawn to a method for identifying a substance modulating Pyk2 binding protein activity.

Group V, claim(s) 29-31, drawn to a method for treating a cancer by administering to a patient substance that modulate the activity of a Pyks binding protein.

Group VI, claim(s) 29-31, drawn to a method for treating a cardiovascular disease by administering to a patient substance that modulate the activity of a Pyks binding protein.

Group VII, claim(s) 29-31, drawn to a method for treating a neurodegenerative disease by administering to a patient substance that modulate the activity of a Pyks binding protein.

Group VIII, claim(s) 29-31, drawn to a method for treating an immune disorder by administering to a patient substance that modulate the activity of a Pyks binding protein.

Group IX, claim 32, drawn to a method for treating a disease with antisense oligonucleotide that inhibits the expression of Pyk2 binding protein.

Group X, claim(s) 34, drawn to a method for detection of nucleic acid encoding a Pyk2 binding protein as indication of a cancer.

Group XI, claim(s) 34, drawn to a method for detection of nucleic acid encoding a Pyk2 binding protein as indication of a cardiovascular disease.

Group XII, claim(s) 34, drawn to a method for detection of nucleic acid encoding a Pyk2 binding protein as indication of a neurodegenerative disease.

Art Unit: 1642

Group XIII, claim(s) 34, drawn to a method for detection of nucleic acid encoding a Pyk2 binding protein as indication of an immune disorder.

Group XIV, claim(s) 35-36, drawn to an antisense oligonucleotide that inhibits the expression of Pyk2 binding protein.

Claim 28 link(s) inventions V- VIII and claim 33 link(s) inventions X-XIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 28 or 33. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions listed as Groups I, II, X, XI, XII, and XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: PCT Rule 13.2 and 37 C.F.R. 1.475 define "special technical feature" as those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." 37 C.F.R. 1.475(d) states that, if multiple products, processes of manufacture, or uses are claimed, the first mentioned in the claims will be considered as the main invention, along with each of the other categories related thereto. The main invention is an isolated DNA sequence comprising a nucleotide sequence encoding a polypeptide having of SEQ ID NO: 1 or 2. Thomas et al., (WO98/36065) disclose a polypeptide, which is 99.6 % identical to the amino acid sequence of SEQ ID NO: 1 as evidenced by sequence search result (exhibit A). Therefore, no special technical feature exists for Group I as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. Since the main invention lacks a "special technical feature,"

Art Unit: 1642

unity of among the nucleic acid (group I), the protein (group II) and the first method of using or making the first product (group X, XI, XII, or XIII) is lacking and restriction is proper. Note that PCT Rule 13 does not provide for multiple products or methods within a single application.

In addition, according to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions.

Inventions V, VI, VII, and VIII are directed to a method for treating a disease by administering a patient a substance that modulated the activity of a Pyks binding protein but each group has a different special technical feature not shared by the remaining groups. Group V is directed to a method for treating cancer, which has a special technical feature of a cancer patient not shared by any of the remaining groups. Group VI is directed to a method for treating cardiovascular disease, which has a special technical feature of heart disease not shared by any of the remaining groups. Group VII is directed to a method for treating neurodegenerative disease, which has a special technical feature of neurodegenerative disease not shared by any of the remaining groups. Group VIII is directed to a method for treating immune disorder, which has a special technical feature of immune disorder not shared by any of the remaining groups.

Invention X, XI, XII, and XIII are directed to a method for detection of nucleic acid encoding a Pyk2 binding protein as indication of a disease, but each group has a different special technical feature not shared by the remaining groups. Invention X is directed to a method for detection of nucleic acid encoding a Pyk2 binding protein as indication of cancer, which has a special technical feature of cancer not shared by any of the remaining groups. Invention XI is directed to a method for detection of nucleic acid encoding a Pyk2 binding protein as indication of cardiovascular diseases, which has a special technical feature of cardiovascular disease not shared by any of the remaining groups. Invention XII is directed to a method for detection of nucleic acid encoding a Pyk2 binding protein as indication of neurodegenerative disease, which has a special technical feature of neurodegenerative disease not shared by any of the remaining groups. Invention XIII is directed to a method for detection of nucleic acid

Art Unit: 1642

encoding a Pyk2 binding protein as indication of immune disorder, which has a special technical feature of immune disorder not shared by any of the remaining groups.

Invention IX, directed to a method for treating a disease with antisense oligonucleotide that inhibiting the expression of Pyk2 binding protein, does not share or corresponding a special technical feature with the other method groups (V-VIII and X- XIII), which are directed to method of treating or detection diseases in patients as discussed above. The special technical feature of invention IX is treating a disease with antisense oligonucleotide not shared by any of the groups V-VIII and X-XIII.

Invention IV, directed to a method for identifying a substance modulating Pyk2 binding protein activity, does not share or corresponding a special technical feature with the other method groups (V- XIII), which are directed to method of treating or detection diseases in patients as discussed above. The special technical feature of invention IV is identifying a substance modulating Pyk2 binding protein activity not shared by any of the groups V- XIII.

Invention III of antibody and invention XIV of antisense do not share or corresponding a special technical feature because the products do not share a common structure, common property, or common activity.

Election of species

This application contains claims directed to the following patentably distinct species of the claimed invention:

- A. Pap α (SEQ ID NO: 1) or Pap β (SEQ ID NO: 2) (specification page 33 and figure 1).
- B. Pyk2 or Sac

In the event that applicant elects one of the inventions I-XIII, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from A for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that applicant elects invention IV, applicant is also required under 35 U.S.C. 121 to elect a single disclosed species from B for prosecution on the merits to which the claims shall be

Art Unit: 1642

restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Art Unit: 1642

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Dowining for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

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SHEELA HUFF
PRIMARY EXAMINER